UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,143	10/16/2003	Craig Bonsignore	CRD-5055	8245

27777 7590 04/24/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,143	BONSIGNORE ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 3/30/2006 have been fully considered but they are not persuasive. Amended claim 1 does not add a patentable difference with regards to the 35 U.S.C. 102(b) rejections over Alt et al. (U.S. 6,251,134). Applicant states that Alt et al. does not disclose the offset bridge design as claimed in amended Claim 1. The bridging element on one stent segment is offset radially with respect to the at least one bridging element on an adjacent stent segment. In this case, each bridging element on one segment is offset radially from every other bridging element of the adjacent stent segment excluding the bridging element of the adjacent stent segment that is longitudinally aligned.

2. In regards to the provisional statutory type 35 U.S.C. 101 double patenting rejection, applicant mentioned that copending Application 10/688,171 has been amended. However, the examiner has not received an amendment for copending Application 10/688,171. Therefore, in light of the amended claim 1 of the instant application, the provisional 35 U.S.C. 101 double patenting rejection has been changed from statutory type to nonstatutory type.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/688,171 in view of Schatz (U.S. 5,902,332). Claims 1-9 of copending Application No. 10/688,171 claim the invention substantially but fail to claim that at least one bridging element on one stent segment is offset radially with respect to the at least one bridging element on an adjacent stent segment.

4. However, Schatz discloses that it is old and well known in the art to provide an expandable medical device that at least one bridging element on one stent segment offset radially with respect to the at least one bridging segment on an adjacent stent segment. Schatz further discloses that radially offset bridging elements permit flexibility between the grafts or prostheses, thereby allowing the device to flexibly bend, or articulate with respect to the longitudinal axis of the device so as to be able to negotiate curves or bends found in body passageways (col. 10 lines 44-48, and col. 10 line 58-col. 11 line 6). Therefore, it would have been obvious to one of ordinary skill in the art to modify the claims of copending Application No. 10/688,171 to include the limitation of at

least one bridging element on one stent segment is offset radially with respect to the at least one bridging element on an adjacent stent segment in order to increase the flexibility of the stent.

This is a provisional obviousness-type double patenting rejection.

Claim Objections

5. (Amended) Claim 1 is objected to because of the following informalities: the word "least" is missing on line 7 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (U.S. 6,251,134).

8. Regarding Claim 1, Alt et al. discloses a medical device with multiple, independent, self-expanding stent segments, each stent segment including a plurality of longitudinal struts (44), a plurality of loops connecting adjacent struts (41 and 42), at least one bridging element (34) and at least one receptacle (35) (Fig 3). The bridging element is configured to be releasably engaged with the receptacle on an adjacent stent segment (Fig. 3; col. 4, lines 19-50; see also the illustration following para.11 of this office action). The at least one bridging element on one stent segment is offset radially with respect to

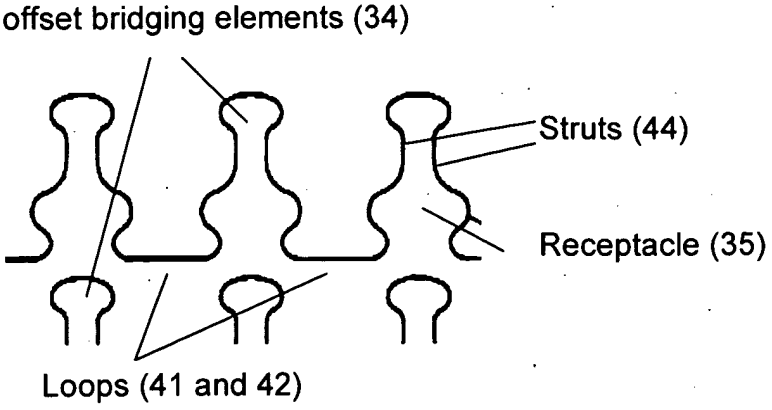
the at least one bridging element on an adjacent stent segment. (See the drawings following paragraph 12 of this office action, which illustrate radially offset bridging elements).

9. Regarding Claim 2, Alt et al. discloses the medical device as stated above wherein the at least one bridging element comprises an elongate member extending from one of the plurality of loops and having a free end with a mating protrusion (Fig 3, "34").

10. Regarding Claim 3, Alt et al. discloses the medical device as stated above further including at least one receptacle configured as a space between adjacent longitudinal struts that defines a cavity for the elongate member and protrusion member (Fig 3, "35").

11. Regarding Claim 4, Alt et al. discloses the medical device as stated above wherein the cavity and the mating protrusion have a substantially oval shape (Fig 2, "34" and "35").

12. Regarding Claim 7, Alt et al. discloses the medical device as stated above, wherein the plurality of struts and the plurality of loops form a substantially S-shaped configuration (Fig 3).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-4 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Chew et al. (U.S. 2003/0135266) in view of Schatz (U.S. 5,902,322).

14. Regarding Claim 1, Chew et al. discloses a medical device with multiple, independent, self-expanding stent segments, each stent segment including a plurality of longitudinal struts (54), a plurality of loops connecting adjacent struts, at least one bridging element (62) and at least one receptacle (64). The bridging element is configured to be releasably engaged with the receptacle on an adjacent stent segment.

15. Regarding Claim 2, Chew et al. discloses the medical device as stated above wherein the at least one bridging element comprises an elongate member extending from one of the plurality of loops and having a free end with a mating protrusion (Fig 5B, "62").

16. Regarding Claim 3, Chew et al. discloses the medical device as stated above further including at least one receptacle configured as a space between adjacent longitudinal struts that defines a cavity for the elongate member and protrusion member (Fig 5B, "64").

17. Regarding Claim 4, Chew et al. discloses the medical device as stated above wherein the cavity and the mating protrusion have a substantially oval shape (Fig 5C, "64" and "62").

18. Regarding Claim 7, Chew et al. discloses the medical device as stated in paragraph 1, wherein the plurality of struts and the plurality of loops form a substantially S-shaped configuration (Fig 5B). The following illustration is taken from Fig 5B of Chew et al. and has a strut and loop labeled.

19. Chew et al. fails to disclose that the bridging element on one stent segment is offset radially with respect to the at least one bridging segment on an adjacent stent segment.

20. However, Schatz discloses that it is old and well known in the art to provide an expandable medical device that at least one bridging element on one stent segment offset radially with respect to the at least one bridging segment on an adjacent stent segment. Schatz further discloses that radially offset bridging elements permit flexibility between the grafts or prostheses, thereby allowing the device to flexibly bend, or articulate with respect to the longitudinal axis of the device so as to be able to negotiate curves or bends found in body passageways (col. 10 lines 44-48, and col. 10 line 58-col. 11 line 6). This radially offset bridging design can be achieved by placing bridging element (62) and receptacle (64) on different strut elements such that the bridging element and receptacle of one stent segment are not aligned longitudinally. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Chew et al. to include at least one bridging element on one stent segment

which is offset radially with respect to the at least one bridging element on an adjacent stent segment made obvious by Schatz in order to increase flexibility for easier navigation of the body passageways.

21. Claims 5, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. in view of Davila et al. or Chew et al. in view of Schatz and in further view of Davila et al. (U.S. 6,863,685). In regards to claims 5 and 6, Alt et al. and modified Chew et al. both describe the invention substantially as described above, further disclosing that the medical device is made of a material that renders the stent self-expandable (claim 7, and para. [0019], respectively). Alt et al. and modified Chew et al. both fail to disclose that the material is a superelastic alloy.

22. Davila et al. discloses that it is old and well known in the art to make a stent from a superelastic alloy such as Nitinol. Davila et al. further discloses that it is old and well known in the art to construct a self-expandable stent from an alloy comprising about fifty percent to about sixty percent Nickel and the remainder titanium. Davila et al. states that the superelastic design of the stent makes it crush recoverable which makes it useful as a stent or frame for any number of vascular devices in different applications (col.6, lines 32-45). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Alt et al. or Chew et al. to include the improvements disclosed by Davila et al. in order to gain the advantages of a medical device that is crush recoverable.

23. Regarding claims 8 and 9, Alt et al. and modified Chew et al. each disclose the invention substantially as described above, but fail to disclose the addition of one or more radiopaque markers.

24. Davila et al. discloses that it is old and well known in the art to use radiopaque markers in a stent medical device. Davila et al. further discloses that radiopaque markers ensure proper positioning of the device within a lumen (col. 5, lines 9-11). Also, Davila et al. states, the markers may be positioned at other locations on the stent (col. 12, lines 52-53) and markers may be utilized to determine when and if a stent is fully deployed (col. 10, lines 64-65). Therefore, it would have been obvious to one of ordinary skill in the art to modify Alt et al. or Chew et al. to include the improvements made obvious by Davila et al. in order to gain the advantage of being able to ensure proper positioning of the device within a lumen. Positioning the markers into the mating protrusion would have been obvious in order to determine when and if each segment of the stent is fully deployed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS
4/14/2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/17/06.